

November 26, 2003

Office of Nutritional Products

Labeling and Dietary Supplements (HFS-810)

**FDA** 

P.O. Box 199 200 C Street, SW

Washington, DC 20204

RE: Notification for Statement on Dietary Supplement

Dear Sir/Madam:

110 South Garfield

In compliance with the Dietary Supplement Health and Education Act of 1994, Highland Laboratories, 110 S Garfield, PO Box 199, Mt. Angel, Oregon 97362, hereby makes its official notification under Section 101.93 that it has included a statement listed in Section 403(r)(6) of the Federal Food, Drug, Cosmetic Act on its label. Accordingly, enclosed please find two (2) copies of this Notification.

in the minimum or my

Mt. Angel, OR 97362

503-845-9223

1-800-547-0273

FAX 503-845-6364

	Company	Product Name	Dietary Ingredients		Statements
	Highland	NutriSilk	Beta Carotene 10,000 IU		Hair, Skin, &
	Laboratories		Vitamin	300 mg	Nails Support
			Vitamin E	100 IU	
			Riboflavin	10 mg	Please see
			Niacin	30 mg	attachment 1
į			Niacinamide	30 mg	
			Vitamin B-6	30 mg	
			Folic Acid	400 mcg	
			Biotin	2,000 mcg	
			Pantothenic Acid 200 mg		
			Zinc	10 mg	
			Inositol	450 mg	
		•	Unsaturated L		
			Complex	300 mg	
	· !		Glycine	300 mg	
			Gelatin	300 mg	
			P.A.B.A.	100 mg	
			L-Cysteine	100 mg	
			L-Tyrosine	50 mg	
			Siberian Ginseng Root		
			50:1 Ext	5 mg	
			Other ingredients:		
			Gelatin (100%		

email: highInd@pdx.oneworld.com

975 0162 LET 13437

preservative-free from capsule shell), natural silica and silicates.	
No corn, salt, yeast, wheat, milk & egg products, sugar, starch, or preservatives.	

I hereby certify that the information presented and contained in this notice is complete and accurate, and my files contain substantiation that the statements made are truthful and misleading.

Sincerely,

Candis L. Scott

**CEO Highland Laboratories** 

Candis L. Seatt

## NutriSilk™ Hair, Skin, Nails Support

What do our hair, skin, and nails have in common? They're all meant to protect us in some way. Our hair helps regulate body temperature; skin protects us from the elements pollution, and bacteria and allows us to feel heat, cold, touch, pressure, and pain. The skin helps us maintain a constant body temperature and discharges toxins via perspiration. Our nails, finger and toe, probably don't protect us now as much as they did in the past when they acted much as talons or claws. However, fingernails can be a handy tool. We'll take a closer look one by one.

We'll start with the skin. Did you know that the skin is the body's largest organ? Did you know that on average it weighs about 5 pounds? Did you know that it actually has its own moisturizing system? Pretty incredible!

Obviously, skin is more complicated than it looks. For example, there are two layers: The dermis (thicker under-layer) and the epidermis (outer layer). Our skin is constantly rebuilding and replenishing itself. In fact, by the time cells reach the outer layer of the epidermis, they are already dead and have been transformed into keratin.

The dermis is made mainly of collagen. Collagen is considered the "glue" cementing cells together. When we suffer a cut, for example, it's collagen that binds the cells back together.

 Vitamin C - the body does not produce vitamin C, which is essential for the formation of collagen.

- Niacin (B-3) & Niacinamide both are needed for proper circulation.
- Zinc Required for protein synthesis and collagen formation.
- Glycine -- is found in high concentrations in the skin and connective tissues.
- Beta Carotene excellent antioxidant, promotes healthy skin, teeth, and hair.

Now that we know skin's function, let's look at hair. Hair helps our body regulate temperature. The average human head has 140,000 hairs on it! That's a lot of hair.

Under a microscope, a hair looks sort of like an armadillo shell. Tiny scales lay end-to-end (much like roofing tile) on the outside to protect the cortex on the inside.

These "scales" are what give hair shine. When they lay flat, they reflect light. When they're damaged by over treatment or pollution for example, your hair may get a "frizzy" look to it and tangle more easily. The scales have been disturbed and are no longer laying flat.

It may not be possible to make hair grow faster, but it is possible to nourish it from the inside as well as the outside. A good shampoo and conditioner can increase the moisture content; while making sure you're eating right and exercising will help ensure a healthy head of hair.

 Biotin - Required by all organisms, a deficiency can hair loss.

- Pantothenic Acid helps the body metabolize protein, the main component of hair.
- PABA a basic constituent of folate; helps in the assimilation of pantothenic acid.
- *L-Tyrosine* Aids in the production of melanin, which is the pigment responsible for skin and hair color.
- Vitamin E aids in the stabilization of Vitamin A. Increases oxygen intake supporting improved blood circulation to the scalp.

Let's go back to keratin for a moment. Keratin is a protein and is found not only in our skin but also our hair and nails.

Our fingernails, toenails, and hair much like skin, begin as a living organism. By the time the hard nail or hair is formed, it's dead. Which, if you think about it, is actually quite convenient. It makes it easy to get a haircut or to trim your nails without pain. That's not to say that a bad haircut can't be painful...

- Folic Acid helps the body form red blood cells and helps in the formation of genetic material.
- L-Cysteine sulfur-containing amino acid. Aids in the formation of skin and keratin. Keratin in the chief component of finger and toenails.
- Riboflavin facilitates the use of oxygen by the tissues of hair, skin, and nails.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or